(iii) Documentation of the donor's blood type accompanies the organ to the hospital where the transplant will take place.

(3) The established protocols must be reviewed regularly with the transplant programs to incorporate practices that have been shown to maximize organ donation and transplantation.

(e) *Documentation of beneficiary information.* If the intended beneficiary has been identified prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended organ recipient's ranking in relation to other suitable candidates and the recipient's OPTN identification number and blood type.

(f) *Donation after cardiac death.* If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:

(1) Criteria for evaluating patients for donation after cardiac death;

(2) Withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support;

(3) Use of medications and interventions not related to withdrawal of support;

(4) Involvement of family members prior to organ recovery;

(5) Criteria for declaration of death and the time period that must elapse prior to organ recovery.

(g) *Organ allocation.* The OPO must have a system to allocate donated organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in §486.320 of this part.

(h) *Organ placement.* The OPO must develop and implement a protocol to maximize placement of organs for transplantation.

§486.346 Condition: Organ preparation and transport.

(a) The OPO must arrange for testing of organs for infectious disease and tissue typing of organs according to current standards of practice. The OPO must ensure that testing and tissue typing of organs are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

(b) The OPO must send complete documentation of donor information to the transplant center with the organ, including donor evaluation, the complete record of the donor's management, documentation of consent, documentation of the pronouncement of death, and documentation for determining organ quality. Two individuals, one of whom must be an OPO employee, must verify that the documentation that accompanies an organ to a transplant center is correct.

(c) The OPO must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival without compromise to the quality of the organ. The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two individuals, one of whom must be an OPO employee, that information listed on the labels is correct.

(d) All packaging in which an organ is transported must be marked with the identification number, specific contents, and donor's blood type.

§486.348 Condition: Quality assessment and performance improvement (QAPI).

The OPO must develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation services, including services provided under contract or arrangement.

(a) *Standard: Components of a QAPI program.* The OPO's QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management, timeliness of on-site response to hospital referrals, consent practices, organ recovery and placement, and organ packaging and transport. The OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained.